UNITED STATES DISTRICT COURT
DISTRICT OF NEW MEXICO
TENTH CIRCUIT

JERMAINE D. DOSS
PLAINTIFF

CV 17-866

V.

16CR845-MV

JANSSEN PHARMACEUTICAL, INC.
JOHNSON & JOHNSON CO.
DEFENDANT,

MOTION FOR PRODUCT LIABILITY CLAIM

This is in reference to the drug Risperdal. I am bringing befourth the court and filing A civil comptaint under a product Liability claim. The drug Risperdal which was manfactured and distrubuted in the United States, by Janssen Pharmaceutical, Inc an enity of Johnson&Johnson. Liability imposed on a manfacture or seller for a - defective and unreasonably dangerous product. As a result of me taking the prescription drug Risperdal. I have suffered from mental - duress, humilation, grief, fright, shock, or indignity. As, well as suffering from developing gynecomastia or breast-enlargement. In order to identify the purpose

of Congress," it is appropriate to briefly review the history of federal regulations of drugs and drug labeling. In 1906, Congress enacted its first significant public health law the Federal Food and Drugs Act, ch. 3915 34 Stat. 768. The Act which prohibited the manufacture or interstate shipment of adulterated or misbranding drugs, supplemented the protection for consumers already provided by state regulations and common-law liability. In the 1930's Congress became increasingly concerned about unsafe drugs and fraudulent marketing, and it enacted the Federal Food, Drug, and Cosmetic Act (FDCA) ch. 675, 52 Stat. 1040, as amended, 21 U.S.C. § 301 et seq. The Act's most substantial innovation was it provision for premarket approval of new drugs. It required every manufacturer to submit a new drug Application, including reports of investigations and specimens of proposed labeling, to the FDA for review. Until its Application became effective, a manfacturer was prohibited from distributing a drug. The FDA could reject an Application if it determined that the drug was not safe for use as labeled, though if the agency failed to act an Application became effective 180 days after the filing. FDCA § 505(c) 52 Stat. 1052 In 1962, Congress amended the FDCA and shifted the burden of proof from the FDA to the manfacturer. Before 1962 the agency had to prove harm to keep a drug out of the market, but the amendments required the manufacturer to demonstrate that its

drug was "safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling" before it could distribute the drug. §§ 102(d) 104(b) 76 Stat. 781, 784. In addition, the amendments required the manfacturer to prove the drug's effectiveness by introducing "substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling." § 102(d), id, at 781

As it enlarged the FDA's power to "protect the public health" and "assure the safety, effectiveness and reliability of drugs," id at 780, Congress took care to preserve State law. The 1962 amendments added a saving clause, indicating that a provision of state law would only be invalidated upon a "direct and positive conflict" with the FDCA § 202 id at 793. Consistent with that provision, State common-law suits "continued unabated despite... FDA regulations." Riegel v. Medtronic Inc., 552 U.S ___, ___, 128 S.Ct 999, 1017, 169 L.Ed.2d 892 (2008)(GINSBURG, J., dissenting); see ibid., n. 11 (collecting state cases). And when Congress enacted an express pre-emption provision for medical devices in 1976, see § 521, 90 Stat. 574 (codified at 21 U.S.C. § 360K(a)), it declined to enact such a provision for prescription drugs. In 2007 after Levine's injury and lawsuit, Congress again amended the FDCA. 121 Stat 823. For the first time, it granted the FDA statutory authority to require a manfacturer to change

its drug label based on safety information that becomes available after a drug's initial approval. § 901(a), id, at 924-926. In doing so, however, Congress did not enact a provision in the Senate bill that would have required the FDA to preApprove all changes to drug labels. See S. 1082 110th Cong., 1st Sess, § 208, pp, 107-114(2007)(as passed)(proposing new § 506D) Instead it adopted a rule of construction to make it clear that manfacturer remain responsible for updating their labels. See 121 Stat. 925-926. In keeping with Congress decision not to pre-empt common-law tort suits, it appears that the FDA traditionally regarded state law as a complementary form of drug regulation. The FDA has limited resources to monitor the 11,000 drugs on the market, and manfacturers have superior access to information about their drugs, especially in the postmarketing phase As new risks emerge. State tort suits uncover unknown drug hazards and provide incentives for drug manfacturers to disclose safety risks promptly. They also serve a distinct compensatory function that may motivate injured persons to come forward with information. failure-to-warn actions in particular, lend force to the FDCA's premise that manfacturers, not the FDA, bear primary responsibility for their drug labeling At all times. Thus, the FDA long maintained that state law offers an additional, and important, layer of consumer protection that complements FDA regulations Drug manfacturers are also required to "establish and maintain records and make reports to the FDA about "[a]ny adverse events associated with the use of a drug

in humans, whether or not considered drug related." after it has recieved federal Approval. §§ 314.80(a),(c),(j). In addition, the manfacturer must make periodic reports about "adverse drug experiences (for example labeling changes or studies initiated)." §§ 314.80(c)(2)(i)-(ii) When such records and reports are not made, the FDA can withdraw its Approval of the drug. ("The Secretary may... withdraw the Approval of an application... if the Secretary finds... that the applicant has failed to establish a system for maintaining required records or has repeatly or — deliberately failed to maintain such records or to make required reports"). The FDA may also determine that a drug is no longer safe for use based on "clinical or other experience, tests, or other scientific data." After the FDA approves a drug, the manfacturer remains under an obligation to investigate and report any adverse events associated with the drug, see 21 CFR § 314.80 ~~U.S.C.~~ 314.81 and must periodically submit any new information that may affect the FDA's previous conclusions about the safety, effectiveness, or labeling of the Drug. 21 U.S.C § 355(k) IF the FDA finds that the drug is not "safe" when used in accordance with its labeling the Agency "shall" withdraw its Approval of the drug. The FDA also "shall" deem a drug "misbranded" "if" it is dangerous to health when used in the dosage manner or with the frequency or duration prescribed, recommended or suggested in

the labeling thereof." § 352(j)

Strict liability for a defective product being "Risperdal" that does not require the plaintiff to have privity of contract with the seller or manufacturer — called also product liability

Product Liability:
Preemption - Preemption of failure-to-warn action by FDA labeling requirements. Wyeth v. Levine No. 06-1249 Jan. 18, 2008, 128 S.Ct. 1118 Levine v. Wyeth 944 A.2d 179 (Vt. 2006 [Pet. Brief: 2008 WL 2273067 Resp. Brief 2008 3285388; Reply Brief 2008 WL 4264481.]

I intially started the Drug Risperdal (Risperidone) in 2012 at VA Medical Center in Seattle WA. In which Im still waiting on the requested medical records. I restarted the Drug Risperdal (Risperidone) at the Torrance County Detention Facility Authorizing Provider Ortiz, Anne M. D Adminstered Dec. 23. 15) I was diagnosed with breast-enlargement in late 2016 while being house at the Regional Justice Center which is documented in my medical records. I was also housed at Federal Detention Center in SeaTac Wa. During Jan, 2016 to May of 2016 and at that time I was As well prescribed Risperdal. I was also on the prescripton drug Risperdal (Risperidone) while housed at the Regional Justice Center in which it's documented. Kent, Wa

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RECEIVED
At Albuquerque NM
AUG 22 2017
MATTHEW J. DYKMAN
CLERK

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